RUKOBIA: for people living with multidrug-resistant (MDR) HIV-1 whose current ARV regimens are unsuccessful[1]

A first-in-class attachment inhibitor that directly targets HIV-1 to protect CD4+ T-cells[1,2]

Durable virologic suppression demonstrated over 96 weeks in PLWH who were previously unable to construct a successful regimen[2]

Robust CD4+ T-cell recovery[2]

BRIGHTE is a Phase 3, partially randomized trial in HTE participants with confirmed HIV-1 RNA ≥400 copies/mL. The randomized cohort (double-blind, placebo-controlled through Day 8, then open-label) enrolled 272 participants who had 1 or 2 ARV classes remaining due to resistance, intolerability, or contraindications. The primary endpoint was the adjusted mean decline in HIV-1 RNA at Day 8: 0.79 $\log_{10}$ copies/mL (RUKOBIA 600-mg BID + failing regimen, n=201) vs 0.17 $\log_{10}$ copies/mL (placebo + failing regimen, n=69); difference: -0.625 (95% CI: -0.810, -0.441); *P*<0.0001. At Week 96, 60% of participants were virologically suppressed, an increase from 53% at Week 24. The mean increase in CD4+ T-cell counts from baseline at Week 96 was 205 cells/mm^3. The most common adverse reaction (all grades) observed in ≥5% of participants was nausea (10%).[2]

RUKOBIA provides a foundation for optimizing HTE regimens

ARV=antiretroviral; BID=twice daily; CI=confidence interval; HIV-1=human immunodeficiency virus type-1; HTE=heavily treatment-experienced; PLWH=people living with HIV-1.

INDICATION

RUKOBIA, in combination with other antiretrovirals (ARVs), is indicated to treat HIV-1 infection in heavily treatment-experienced adults with multidrug-resistant HIV-1 infection failing their current ARV regimen due to resistance, intolerance, or safety considerations.

IMPORTANT SAFETY INFORMATION

Contraindications

- Do not use in patients with previous hypersensitivity to fostemsavir or any of the components of RUKOBIA.
- Do not use RUKOBIA in patients receiving strong cytochrome P450 (CYP)3A inducers, including but not limited to enzalutamide, carbamazepine, phenytoin, rifampin, mitotane, and St John's wort *(Hypericum perforatum)*.

Warnings and precautions

Immune Reconstitution Syndrome, including the occurrence of autoimmune disorders with variable time to onset, has been reported with the use of RUKOBIA.

Please see additional Important Safety Information for RUKOBIA throughout. Please see full Prescribing Information for RUKOBIA.

Rukobia (fostemsavir) extended-release tablets · 600 mg

Prescribe RUKOBIA as part of an optimized ARV regimen

One 600-mg tablet

Do not chew, crush, or split.

Tablet shown is not actual size.

Taken **twice daily**

With or without food

Without dose adjustments for renal or hepatic impairment, regardless of severity

Visit RUKOBIAhcp.com to learn more about dosing and drug interactions

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

QTc Prolongation with Higher than Recommended Dosages: RUKOBIA at 2,400 mg twice daily has been shown to significantly prolong the QTc interval of the electrocardiogram. Use RUKOBIA with caution in patients with a history of QTc interval prolongation or in patients with relevant pre-existing cardiac disease or who are taking drugs with a known risk of Torsade de Pointes. Elderly patients may be more susceptible to drug-induced QT interval prolongation.

Elevations in Hepatic Transaminases in Patients with Hepatitis B or C Virus Co-infection:

- Monitoring of liver chemistries is recommended in patients with hepatitis B and/or C co-infection.
- Diligence should be applied in initiating or maintaining effective hepatitis B therapy when starting RUKOBIA in patients co-infected with hepatitis B.

Please see additional Important Safety Information for RUKOBIA throughout. Please see full Prescribing Information for RUKOBIA.

Rukobia (fostemsavir) extended-release tablets · 600 mg

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings and precautions (cont'd)

Adverse Reactions or Loss of Virologic Response Due to Drug Interactions with concomitant use of RUKOBIA and other drugs may occur (see Contraindications and Drug Interactions).

Adverse reactions

- The most common adverse reaction (all grades, randomized cohort) observed in ≥5% of subjects was nausea (10%).
- 81% of adverse reactions reported with RUKOBIA were mild or moderate in severity.

Drug interactions

- See the full Prescribing Information for RUKOBIA for a complete list of significant drug interactions.
- Temsavir may increase plasma concentrations of grazoprevir and voxilaprevir. Use an alternative hepatitis C virus regimen if possible.
- Use the lowest possible starting dose for statins and monitor for statin-associated adverse events.
- Patients receiving RUKOBIA should not take doses of estrogen-based therapies, including oral contraceptives, that contain more than 30 mcg/day of ethinyl estradiol. Caution is advised particularly in patients with additional risk factors for thromboembolic events.

Use in specific populations

- **Pregnancy:** There are insufficient human data on the use of RUKOBIA during pregnancy to definitively assess a drug-associated risk for birth defects and miscarriage. An Antiretroviral Pregnancy Registry has been established.
- **Lactation:** Breastfeeding is not recommended due to the potential for HIV-1 transmission, developing viral resistance, and adverse reactions in a breastfed infant.

REFERENCES: 1. Ackerman P, Thompson M, Molina JM, et al. Long-term efficacy and safety of fostemsavir among subgroups of heavily treatment-experienced adults with HIV-1. *AIDS*. 2021;35(7):1061-1072. **2.** Lataillade M, Lalezari JP, Kozal M, et al. Safety and efficacy of the HIV-1 attachment inhibitor prodrug fostemsavir in heavily treatment-experienced individuals: week 96 results of the phase 3 BRIGHTE study. *Lancet HIV*. 2020;7(11):740-751.

Please see additional Important Safety Information for RUKOBIA throughout.
Please see full Prescribing Information for RUKOBIA.

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